OCT 31 2003

K031862

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Technological Considerations:

The SpineRx - LDM (lumbar decompression machine) combines proven characteristics of several predicate devices. The VAX-D ® Therapeutic Table (K951622) effectively applies decompression (distraction) in the prone modality. The DRS System ™ (K981822) applies variable angle (above horizontal) decompression (distraction) in the supine modality. The 3D ActiveTrac (K001712) applies variable angle (above and below horizontal) decompression (distraction). The SpineRx - LDM provides variable angle decompression (distraction) in either prone or supine modality. The broad range of patient positioning variables allows either straight-line (linear) or angled (curvilinear) decompression (distraction) to be concentrated in more specific spinal segments. The harness and restraint system allows safe, effective application of therapeutic traction.

The SpineRx - LDM traction device allows a wide range of selectable functions, force levels and time cycles. Prescribed treatment parameters are selected for each patient and each treatment session. The Vari-Trac II (K862846) has demonstrated the ability to effectively apply traction (distraction) forces in a wide variety of programmable patterns and cycles.

While the general appearance of the SpineRx - LDM is somewhat different than predicate devices, the basic principles of these effective, proven functions and characteristics remain intact and not compromised.

Summary of Safety and Effectiveness:

The SpineRx - LDM, Lumbar Decompression Machine, is intended to provide a variety of treatment options for patients who suffer from some of the most common forms of low back pain. Conditions which may be treated include bulging or protruding discs, herniated discs, degenerative disc disease, posterior facet syndrome and sciatica. The SpineRx - LDM can apply therapeutic decompression (distraction) force to relieve pressure on structures which may produce pain. Decompression can relieve pain by introducing a distraction force (unloading) sufficient to reduce intradiscal pressure and impingement. Therapeutic distraction can be applied in a variety of programmable patterns, cycles and functions. Variable angle positioning in either supine or prone modalities acts to concentrate decompression forces for optimum results. This machine is a prescription device and as such, it should be used under the direct supervision of a qualified medical professional.

1. All machine controls are simple, straight-forward, conveniently placed and easy to use.
2. Traction device is conveniently and appropriately located and all controls easily and readily accessible.
3. Traction device provides wide variety of programmable patterns, cycles and functions.
4. Visual and audio signals provide constant treatment session status and monitoring.
5. Remote kill switch (panic button) allows patient absolute control of traction force application.
6. Sturdy, dependable lower table/bed lift mechanism provides smooth, precise angular positioning.
7. Strategically positioned overhead handrail facilitates patient mounting and dismounting the table/bed.
8. Knee support, cervical wedge and head pillow enhance patient comfort and session effectiveness.
9. All materials and finishes which have patient skin contact meet all industry standards and requirements.

The Vari-Trac II traction device (manufactured under various names) has been is use in this country for more than fourteen years and there are apparently no MDR reports by the manufacturer or any adverse events reported by users of this device. No problems have been experienced during any trails or tests conducted by Spinerx Technology.

Standards and Testing: Performance, Safety, Electrical, Flammability, Biocompatibility

Based on information we have received from either the manufacturers or distributors, all of the materials used for this machine either meet or exceed standards for this application. All materials on this device have been used in the past and are currently being used on marketed devices without any known or reported adverse effects or events.

We have talked with our liaison person in the FDA Southwest Region Office in Dallas, Texas and also the FDA-CDRH Office in Rockville, Maryland. We were directed to the Declaration of Conformance section regarding standards. Even though we have built two prototype machines, we have not actually built the machine which is the subject of this application. Therefore, we have not conducted tests which demonstrate conformance with applicable standards.

Listed below are some of the standards and requirements to which we will comply.

Electrical - We will confiorm and comply with applicanble UL-2601-1 Standards.

Flammability - All materials and components will meet or exceed flame retardant requirements for this application. e.g. - Upholstery: Naugahyde ® California Fire Regulation (Bulletin 117, Section E), Automotive (MVSS-302), BIFMA (Screen Test, Section 4.6.1.1), Boston Fire Code (BFD IX-1), CID A-A-2950-A (Federal Standard 191A test method 5903), Upholstery Requirements - FAR 25.853
Foam: High Resilience - Manufactured with flame retardant properties (awaiting specs from supplier)
Plywood Bases: Manufactured with flame retardant properties (Title 19 - California Code)
Paints & Finishes: Corvel ® 70 Series is an FDA approved melt mix nylon powder coating.

Biocompatibility - Upholstery material, Naugahyde ®, contains agents effective against bacterial and fungal micro-organisms and is formulated to provide a superior level of disinfectability. Corvel® 70 Series Powder Coat Finishes are FDA approved and have excellent properties for hospital environments.

Formal testing and evaluation have not been performed for the SpineRx - LDM, as of yet.

We will conduct a full battery of tests, electrical, safety, performance, on a completed SpineRx - LDM. This will allow us to document and certify that our machine meets or exceeds all applicable requirements and standards. Our ultimate goal is to comply with standards sufficient to allow us to market internationally as well as domestically.

We have talked with manufacturer's representatives, examined samples, reviewed specifications and spent considerable time and effort to determine which products and materials will best meet the needs and satisfy the requirements of this particular application.

Declaration of Conformance: We affirm that prior to sale, we will conform to all applicable standards and comply with all appropriate testing requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2003

Mr. Hughie Watson
SpineRx Technology
6100 Brittmoore Road, Building S
Houston, Texas 77041

Re: K031862
Trade/Device Name: SpineRx-LDM
Regulation Number: 21 CFR 890.5900
Regulation Name: Powered traction equipment
Regulatory Class: II
Product Code: ITH
Dated: September 10, 2003
Received: September 15, 2003

Dear Mr. Watson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-__. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510 (k) Number (if known): K031862

Device Name: *SpineRx - LDM*

Indications for Use:

The SpineRx - LDM, Lumbar Decompression Machine, is intended to provide a variety of treatment options for patients who suffer from some of the most common forms of low back pain. Conditions which may be treated include bulging or protruding discs, herniated discs, degenerative disc disease, posterior facet syndrome and sciatica. The SpineRx - LDM can apply therapeutic decompression (distraction) force to relieve pressure on structures which may produce pain. Decompression can relieve pain by introducing a distraction force (unloading) sufficient to reduce intradiscal pressure and impingement. Therapeutic distraction can be applied in a variety of programmable patterns, cycles and functions. Variable angle positioning in either supine or prone modalities acts to concentrate decompression forces for optimum results. This machine is a prescription device and as such, it should be used under the direct supervision of a qualified medical professional.

(Please Do Not Write Below This Line - Continue On Other Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:_____ OR Over-The-Counter Use:_____

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031862